

CURRICULUM VITAE

Michael Anthony Carome, MD, FACP
August 2018

CONTACT INFORMATION:

Work Address: Public Citizen
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Washington, DC 20009
Work Telephone: 202-588-7781
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PRESENT POSITIONS:

Director
Health Research Group
Public Citizen
Washington, DC
June 2013-present

Teaching Faculty Associate
Department of Health Policy and Management
Bloomberg School of Public Health
Johns Hopkins University
Baltimore, MD
February 2017-present

PREVIOUS PROFESSIONAL APPOINTMENTS/POSITIONS:

Deputy Director
Health Research Group
Public Citizen
Washington, DC
January 2011-May 2013

Associate Director for Regulatory Affairs
Office for Human Research Protections
Office of Public Health and Science
Office of the Secretary
Department of Health and Human Services
Rockville, MD
June 2002-December 2010

Staff Nephrologist
Nephrology Service
Department of Medicine
Walter Reed Army Medical Center
Washington, D.C.
July 1992-December 2010

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Director
Division of Compliance Oversight
Office for Human Research Protections
Office of Public Health and Science
Department of Health and Human Services
Rockville, MD
September 2000-January 2003

Chief
Compliance Oversight Branch
Division of Human Subject Protections
Office for Human Research Protections
Office of Public Health and Science
Office of the Secretary
Department of Health and Human Services
Rockville, MD
June 2000-September 2000

Chief
Compliance Oversight Branch
Division of Human Subject Protections
Office for Protection from Research Risks
National Institutes of Health
Rockville, MD
February 1999-June 2000

Acting Chief
Compliance Oversight Branch
Division of Human Subject Protections
Office for Protection from Research Risks
National Institutes of Health
Rockville, MD
October 1998-January 1999

Human Subject Protections Coordinator
Compliance Oversight Branch
Division of Human Subject Protections
Office for Protection from Research Risks
National Institutes of Health
Rockville, MD
July 1998-September 1998

Assurance Coordinator
Assurance Branch
Division of Human Subject Protections
Office for Protection from Research Risks
National Institutes of Health
Rockville, MD
October 1997-June 1998

MICHAEL A. CAROME, M.D.
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Assistant Professor of Medicine
Department of Medicine
Uniformed Services University of Health Sciences
Bethesda, Maryland
1992-1998

Chief, Research Review Service
and Assistant Chief
Department of Clinical Investigation
Walter Reed Army Medical Center
Washington, D.C.
1995-1997

Medical Director, Nephrology Laboratory
Nephrology Service
Walter Reed Army Medical Center
Washington, D.C.
1993-1995

Guest Researcher
Renal Cell Biology Section
National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health
Bethesda, Maryland
1990-1993

Instructor
Department of Medicine
Uniformed Services University of Health Sciences
Bethesda, MD
1989-1992

Laboratory Assistant in Microbiology
Department of Biology
Johns Hopkins University
Baltimore, Maryland
1981-1982

EDUCATION:

College: Georgetown University
Washington, D.C.
1977-1981 - B.S., Psychology

Medical School: Case Western Reserve University
Cleveland, Ohio
1982-1986

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Internship/Residency: Internal Medicine
Walter Reed Army Medical Center
Washington, D.C.
1986-1989

Fellowship: Nephrology
Walter Reed Army Medical Center
Washington, D.C.
1989-1992

COMMITTEE APPOINTMENTS:

Department of Medicine Representative
Clinical Investigation Committee
Walter Reed Army Medical Center
1993-1995

Chairperson
Clinical Investigation Committee
Walter Reed Army Medical Center
1995-1997

Co-Chairperson
Human Use Committee/Institutional Review Board
Walter Reed Army Medical Center
1995-1997

Chairperson
Institutional Animal Use and Care Committee
Walter Reed Army Medical Center
1995-1996

Member, Research Committee
National Kidney Foundation of the National Capital Area, Inc
1996-1997

Member, Interdivisional Policy Coordinating Committee
Office for Human Research Protections
Department of Health and Human Services
2001-2010

Ex Officio Member
Secretary's Advisory Committee on Genetics, Health, and Society
Department of Health and Human Services
2003-2010

OHRP Liaison to Subcommittee on Research Involving Children
Secretary's Advisory Committee on Human Research Protections
Department of Health and Human Services
2003-2005

OHRP Liaison to Subpart A Subcommittee
Secretary's Advisory Committee on Human Research Protections
Department of Health and Human Services
2005-2010

Member (Consumer Representative)
Pharmacy Compounding Advisory Committee
Food and Drug Administration
2015-present

RESEARCH GRANTS:

National Kidney Foundation of the National Capital Area Research Grant, 1996-97, Title: Are Stress Proteins Target Antigens in Renal Allograft Recipients? (\$22,300)

EDITORIAL ACTIVITIES:

Editor, *Worst Pills, Best Pills News*, March 2014-present

Editor, *Health Letter*, November 2013-present

Reviewer, *Kennedy Institute of Ethics Journal*, 2016

Reviewer, *JAMA Internal Medicine*, 2014-2015

Reviewer, *PLoS Medicine*, 2012

Reviewer, *Kidney International*, 1993

BOARD CERTIFICATION:

American Board of Internal Medicine
Diplomate in Internal Medicine, 1989
No expiration date

American Board of Internal Medicine
Diplomate in Nephrology, 1992; re-certified 2002
Expired 2012

STATE LICENSES:

Ohio, License #35-04-4155 (1986-1998)
Virginia, License #0101-055891 (1997-present)

HONORS/AWARDS:

Psi Chi, Honorary Society of Psychology, 1980

Graduated magna cum laude, Georgetown University, 1981

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First Place-Basic Science, Fellows Competition, National Kidney Foundation of the National Capital Area, 1992

Army Commendation Medals, 1992, April 1996, November 1996

Bailey K. Ashford Clinical Research Award, Walter Reed Army Medical Center, 1992

Army Achievement Medal, 1992

Public Health Service Bicentennial Unit Commendation, 1998

Public Health Service Commendation Medals, 1999 and 2007

Special Recognition Award for Service in Support of NIH-Wide Grants Management Initiatives, Vision Steering Committee, NIH, 2000

Assistant Secretary for Health's Outstanding Team Performance Award, 2001

Public Health Service Unit Commendations, 2001 and 2005

Public Health Service Crisis Response Service Awards, 2004 and 2006

Public Health Service Outstanding Service Medals, 2004 and 2008

Public Health Service Outstanding Unit Citations, January 24, 2007 and January 26, 2007

Public Health Service Field Medical Readiness Badge, 2007

MILITARY SERVICE:

Branch: US Army Reserve, active duty
Rank/Grade: Major(P)/O-4, Medical Corps
Place: Walter Reed Army Medical Center, Washington, DC
Dates: May 1986-September 1997 (Honorable Discharge)

SERVICE IN THE U.S. PUBLIC HEALTH SERVICE

Category: Medical Officer,
Rank/Grade Captain/O-6, Regular Corps
Places: Office for Protection from Research Risks, National Institutes of Health
Office for Human Research Protections, Office of the Secretary
Rockville, MD
Dates: October 1997-December 2010 (Retired)

CURRENT PROFESSIONAL MEMBERSHIPS AND SOCIETIES:

American College of Physicians, Member, 1990-1993; Fellow 1993-present
Physicians for a National Health Plan, Member, 2011-present

BIBLIOGRAPHY:

PEER-REVIEWED PUBLICATIONS

1. Carome MA, Moore J: Nephrotic syndrome in adults: a diagnostic and management challenge. *Postgrad Med.* 1992;92:209-220.
2. Eliasson AH, Phillips YY, Stajduhar KC, Carome MA, Cowsar JD. Oxygen consumption and ventilation during normal labor. *Chest.* 1992;102:467-471.
3. Peten EP, Striker LJ, Carome MA, Elliot SJ, Yang CW, Striker GE: The contribution of increased collagen synthesis to human glomerulosclerosis: a quantitative analysis of $\alpha 2IV$ collagen mRNA expression by competitive polymerase chain reaction. *J Ex Med.* 1992;176:1571-1576.
4. Moore J, Carome MA. Proteinuria. *Clin in Lab Med.* 1993;13:21-31.
5. Carome MA, Striker LJ, Peten EP, Moore J, Yang CW, Stetler-Stevenson WG, Striker GE. Human glomeruli express tissue inhibitor of metalloproteinase-1 (TIMP-1) mRNA and TIMP-2 protein and mRNA in vivo. *Am J Physiol.* 1993;264:F923-F929.
6. Striker GE, Peten EP, Carome MA, Pesce CM, Schmidt K, Yang CW, Elliot SJ, Striker LJ. The kidney disease of diabetes mellitus (KDDM): A cell and molecular biology approach. *Diabetes/Metabolism Reviews.* 1993;9:37-56.
7. Carome MA, Striker LJ, Peten EP, Elliot SJ, Yang CW, Stetler-Stevenson WG, Reponen P, Tryggvason K, Striker GE. Assessment of 72 kDa gelatinase and TIMP-1 gene expression in normal and sclerotic murine glomeruli. *J Am Soc Nephrol.* 1994;5:1391-1399.
8. Yang CW, Hattori M, Vlassara H, He CJ, Carome MA, Yamato E, Elliot SJ, Striker GE, Striker LJ. Overexpression of TGF- $\beta 1$ mRNA is associated with upregulation of glomerular tenascin and laminin gene expression in diabetic NOD mice. *J Am Soc Nephrol.* 1995;5:1610-1617.
9. Yuan CM, Bohen EM, Musio F, Carome MA. Sub-lethal heat shock and cyclosporine exposure produce tolerance against subsequent cyclosporine toxicity. *Am J Physiol.* 1996;271:F571-F578.
10. Musio F, Carome MA, Bohen EM, Sabnis S, Yuan CM. The effect of glycine on the cis-platin nephrotoxicity and heat shock protein 70 expression in the rat kidney. *Renal Failure.* 1997;19:33-46.
11. Carome MA, Kang YH, Bohen EM, Nicholson DE, Carr FE, Kiandoli LC, Brummel SE, Yuan CM. Distribution of the cellular uptake of phosphorothioate oligodeoxynucleotides in the rat kidney. *Nephron.* 1997;75:82-87.
12. Borrer K, Carome M, McNeilly P, Weil C. A review of OHRP compliance oversight letters. *IRB: Ethics & Hum Res.* 2003;25:1-4.
13. AbuDagga A, Wolfe SM, Carome M, Oshel RE. Cross-sectional analysis of the 1039 U.S. physicians reported to the National Practitioner Data Bank for sexual misconduct, 2003–2013. *PLoS ONE.* 2016 February 3;11(2): e0147800. doi:10.1371/journal.pone.0147800.
14. Zieve A, Carome MA. Manufacturers' promotion of off-label drug use: Implications for drug safety. *Expert Opin Drug Saf.* 2016. DOI: 10.1080/14740338.2016.1186642.

15. Cortes-Puch I, Wesley RA, Carome MA, Danner RL, Wolfe SM, Natanson C. Usual care and informed consent in clinical trials of oxygen management in extremely premature infants. *PLoS One*. 2016 May 18;11(5):e0155005. doi: 10.1371/journal.pone.0155005.
16. Mansour M, Favini N, Carome MA, Wolfe S, Woolhandler S, Himmelstein DU. Accountable care organizations' payments to physicians: Patients should have the right to know. *Am J Public Health*. 2017;107(8):1251-1252.
17. Almashat A, Carome M. Withholding information on unapproved drug marketing applications: The public has a right to know. *J Law Med Ethics*. 2017;45(4, Supplement):46-49.
18. Sorscher S, AbuDagga A, Almashat S, Carome MA, Wolfe SM. Placebo-only-controlled versus active-controlled trials of new drugs for nine common life-threatening diseases. *Open Access J Clin Trials*. 24 April 2018;10:19-28.

MEETING ABSTRACTS

1. Carome MA, Striker LJ, Elliot SJ, Peten EP, Stetler-Stevenson WG, Striker GE. TIMP1 and $\alpha 1$ type IV collagen mRNAs in mouse mesangial cells at low and high density. *J Am Soc Nephrol*. 1991;2:572 (presented at the 24th annual meeting of the American Society of Nephrology, Baltimore, MD, Nov 17-20, 1991).
2. Carome MA, Peten EP, Moore J, Stetler-Stevenson WG, Striker GE, Striker LJ: Tissue inhibitor of metalloproteinase-1 (TIMP-1) and TIMP-2 mRNAs. Detection and quantitation in isolated whole human glomeruli by RT-PCR. *Renal Failure*. 1992;14:609 (presented at the International Meeting on Molecular Approaches to Nephrology: Prospects in Diagnosis and Management, Bari, Italy, March 19-21, 1992).
3. Peten EP, Striker LJ, Carome MA, Garcia-Perez A, Striker GE. Quantitation of $\alpha 1$ and $\alpha 2$ type IV collagen mRNAs in single mouse and human microdissected glomeruli by reverse transcription and competitive polymerase chain reaction (RT-PCR) *Renal Failure*. 1992;14:598 (presented at the International Meeting on Molecular Approaches to Nephrology: Prospects in Diagnosis and Management, Bari, Italy, March 19-21, 1992).
4. Carome MA, Peten EP, Reponen P, Trygvason K, Striker GE, Striker LJ. 72 kDa gelatinase (72GEL) mRNA is expressed in normal mouse glomeruli in vivo and is up-regulated in sclerotic glomeruli. *J Am Soc Nephrol*. 1992;3:578 (presented at the 25th annual meeting of the American Society of Nephrology, Baltimore, MD, Nov 15-18, 1992).
5. Carome MA, Peten EP, Elliot SJ, Moore J, Yang CW, Stetler-Stevenson WG, Striker GE, Striker LJ. Human glomeruli express 72 kDa gelatinase (72GEL), tissue inhibitor of metalloproteinase-1 (TIMP-1), and TIMP-2 mRNAs in vivo. *J Am Soc Nephrol*. 1992;3:651 (presented at the 25th annual meeting of the American Society of Nephrology, Baltimore, MD, Nov 15-18 1992).
6. Peten EP, Carome MA, Elliot SJ, Yang CW, Striker SJ, Striker GE. Expression of $\alpha 2IV$, $\alpha 3IV$, and $\alpha 5IV$ collagen mRNAs in normal and sclerotic adult human glomeruli. *J Am Soc Nephrol*. 1992;3:662 (presented at the 25th annual meeting of the American Society of Nephrology, Baltimore, MD, Nov 15-18, 1992).
7. Peten EP, Yang CW, He CJ, Carome MA, Striker GE, Striker LJ. Late remodeling in glomerulosclerosis. *FASEB J*. 1993;7:A197 (presented at the annual FASEB meeting, March 28-April 1,

1993, New Orleans, LA).

8. Carome MA, Peten EP, Elliot SJ, Stetler-Stevenson WG, Striker GE, Striker LJ. Expression of gelatinase proteins and mRNA and TIMP-1 mRNA by intact mouse glomeruli and mesangial cells in vitro: studies in glomerulosclerosis (presented at the XIIth International Congress of Nephrology, Jerusalem, Israel, June 13-18, 1993).
9. Peten EP, Yang CW, Carome MA, Striker GE, Striker LJ. Phenotypic switch and gene activation in experimental glomerulosclerosis (presented at the XIIth International Congress of Nephrology, Jerusalem, Israel, June 13-18, 1993).
10. Yuan CM, Bohen EM, Carome MA. Induction of heat shock proteins reduces cyclosporine toxicity in LLC-PK cells. *Clin Res.* 1994;42:221A (presented at the annual AFCR Clinical Research Meeting, Baltimore, MD, April 29-May 2, 1994).
11. Carome MA, Kang Y-H, Bohen EM, Nicholson DE, Carr FE, Yuan CM. The distribution of radiolabeled phosphorothioate oligonucleotides (ODNs) within the rat kidney following intravenous administration. *J Am Soc Nephrol.* 1994;5:618 (presented at the 27th annual meeting of the American Society of Nephrology, Orlando, FL, October 26-29, 1994).
12. Salzberg DJ, Carome MA, Musio F, Yuan CM. Induction of the heat shock response reduces cis-platin toxicity in cultured renal epithelial cells. *J Am Soc Nephrol.* 1994;5:930 (presented at the 27th annual meeting of the American Society of Nephrology, Orlando, FL, October 26-29, 1994).
13. Yuan CM, Musio F, Bohen EM, Carome MA. The protective effect of heat shock (HS) on subsequent cyclosporine A (CYA) toxicity in renal epithelial cells in vitro declines concurrently with decreasing Hsp 70 levels. *J Am Soc Nephrol.* 1994;5:934 (presented at the 27th annual meeting of the American Society of Nephrology, Orlando, FL, October 26-29, 1994).
14. Yuan CM, Popham SG, Musio F, Salzberg DJ, Bohen EM, Carome MA. Mannitol protects LLC-PK1 cells from cyclosporine A (CYA) toxicity without induction of heat shock protein 70 (Hsp 70) gene expression. *J Am Soc Nephrol.* 1994;5:934.
15. Yuan CM, Bohen E, Carome M. Betaine exposure inhibits heat shock-induced up-regulation of Hsp70 protein and subsequent tolerance to cyclosporine toxicity in LLC-PK1 cells. *J Am Soc Nephrol.* 1995;6:371 (presented at the 28th annual meeting of the American Society of Nephrology, San Diego, CA, November 5-8, 1995).
16. Bohen EM, Yuan CM, Carome MA. Hydrogen peroxide induces Hsp70 gene expression and protects against subsequent H₂O₂ or cyclosporine (CYA) toxicity in LLC-PK1 cells. *J Am Soc Nephrol.* 1995;6:974 (presented at the 28th annual meeting of the American Society of Nephrology, San Diego, CA, November 5-8, 1995).
17. Pisel GA, Yuan CM, Carome MA. Induction of the heat shock response protects cultured human proximal tubular (HRPT) cells from cyclosporine A (CYA) toxicity. *J Am Soc Nephrol.* 1995;6:1063 (presented at the 28th annual meeting of the American Society of Nephrology, San Diego, CA, November 5-8, 1995).
18. Yuan CM, Bohen EM, Carome MA. Cyclosporine (CYA) induces Hsp70 gene expression and protects against subsequent CYA toxicity in LLC-PK1 cells. *J Am Soc Nephrol.* 1995;6:1067 (presented at the 28th annual meeting of the American Society of Nephrology, San Diego, CA, November 5-8, 1995).

19. Musio F, Carome MA, Bohen EM, Sabnis S, Yuan CM. The effect of glycine on cis-platin nephrotoxicity and heat shock protein 70 expression in the rat kidney. *J Am Soc Nephrol.* 1995;6:985.
20. Carome MA, Bohen EM, Yuan CM. Arachidonic acid (AA) induces Hsp70 gene expression but fails to induce tolerance to subsequent toxin exposure in LLC-PK1 cells. *J Am Soc Nephrol.* 1995;6:975.
21. Carome MA, Bohen EM, Yuan CM. Heat shock induces tolerance against hydrogen peroxide exposure but not against arachidonic acid toxicity in LLC-PK1 cells. *J Am Soc Nephrol.* 1995;6:975.
22. Staley D, Carome M, Yuan C. Effect of calcium on HSP70 gene expression after heat shock or cyclosporine exposure in LLC-PK1 cells. *J Am Soc Nephrol.* 1996;7:1846 (presented at the 29th annual meeting of the American Society of Nephrology, New Orleans, LA, November 3-6, 1996).
23. Salzberg DJ, Carome MA, Yuan CM. Lazaroids block the protective effects of heat shock in LLC-PK1 cells. *J Am Soc Nephrol.* 1996;7:1845 (presented at the 29th annual meeting of the American Society of Nephrology, New Orleans, LA, November 3-6, 1996).

LETTERS TO THE EDITOR

1. Carome MA. Is Informed Consent Always Necessary for Randomized, Controlled Trials? *N Engl J Med.* 1999;341:448-449.
2. Carome MA, Wolf SM. Florbetapir-PET imaging and postmortem beta-amyloid pathology. *JAMA.* 2011;305:1857.
3. Carome M, Wolfe S. Rethinking clinical trials: phase 1 studies insufficient. *Science.* 2011;334:1346.
4. Carome MA. Hospital's response inadequate. *Casper Star Tribune.* March 16, 2012.
5. Carome MA, Wolf SM. As superbug spread, NIH failed in its duty to protect. *The Washington Post.* August 24, 2012.
6. Carome MA, Sorscher S. Compounding pharmacies can be regulated by FDA. *The Washington Post.* April 21, 2013.
7. Carome M, Zieve A. Making generic drug labels safer. *Los Angeles Times.* March 14, 2014.
8. Barbehenn E, Almashat S, Carome M, Wolfe S. Hepatotoxicity of alogliptin. *Clin Pharmacokinet.* 2014;53(11):1055-6.
9. Carome M. The NIH can't be trusted to probe its own alcohol study. *The Washington Post.* March 25, 2018.